# JURISDICTION: FDA OR EPA ?

- GE Animals
- Products for Livestock, Pets, and Wildlife

April 2021

# Purpose of Briefing

- Describe the history and challenges of EPA-FDA jurisdiction
- Describe the 2 product types at issue:
  - GE insects/animals for population control
  - Chemical parasite control products for domestic animals
- Describe staff's 3 possible approaches to resolve jurisdictional impasse

# Background

- Until 1975, products intended to kill "pest" animals met both the FIFRA definition of pesticide and FFDCA definition of drug.
- In 1975, Congress amended the FIFRA pesticide definition to specifically exclude new animal drugs as defined by FFDCA:
  - "articles (other than food) intended to affect the structure or any function of the body of man or other animals."
- Effectuating adequate oversight has become increasingly difficult under paradigm established by 1975 amendment to FIFRA.
  - A series of MOUs have been proposed since 1975 (most recently 2010) but never finalized.
  - Identified need to provide adequate protection for:
    - The environment when animals are GE for population control (i.e., those similar to the GE mosquito) (e.g., GE ticks and mice) that FIFRA can provide.
    - Domestic animals (pets and livestock) whose welfare is not adequately accounted for when registering chemical parasite control products.

# Background:
## Jurisdiction Transfer of GE Animals for Population Control from FDA to EPA

| Year | Action |
|---|---|
| 2009 | FDA publishes Guidance for Industry #187 and asserts jurisdiction over all GE animals |
| 2016 | US National Biotechnology Strategy set forth goal of realigning oversight with traditional regulatory authorities so that genetically engineered insects for population control would be regulated by EPA and USDA |
| 2017 | Impacted by concern over Zika virus transmission and infant encephalitis, FDA makes some progress towards 2016 USG goal and publishes Guidance for Industry #236 which moves GE mosquitoes for population control from FDA to EPA<br>• EPA believes that rationale allowing transfer of mosquito products from FDA to EPA jurisdiction applies equally well to all other GE animals for population control<br>• FDA expresses to EPA concern about potential impact on FDA's purview and potential unanticipated effects on past jurisdictional decisions for chemical products |
| 2020 | EPA regulates Oxitec GE mosquito and issues experimental use permit in April 2020 |

# Current Issues:

## Jurisdiction Transfer of GE Animals for Population Control from FDA to EPA

- These genetically engineered animals can have broad environmental consequences, e.g., gene drives can significantly suppress or even eradicate species. Only EPA under FIFRA has broad enough authorities to address
- Although FDA issued #236, in 2020 FDA sent revised draft Guidance for Industry #187 to OMB, but did not share with EPA, and we have heard that it does not address EPA concerns on other GE animals for population control
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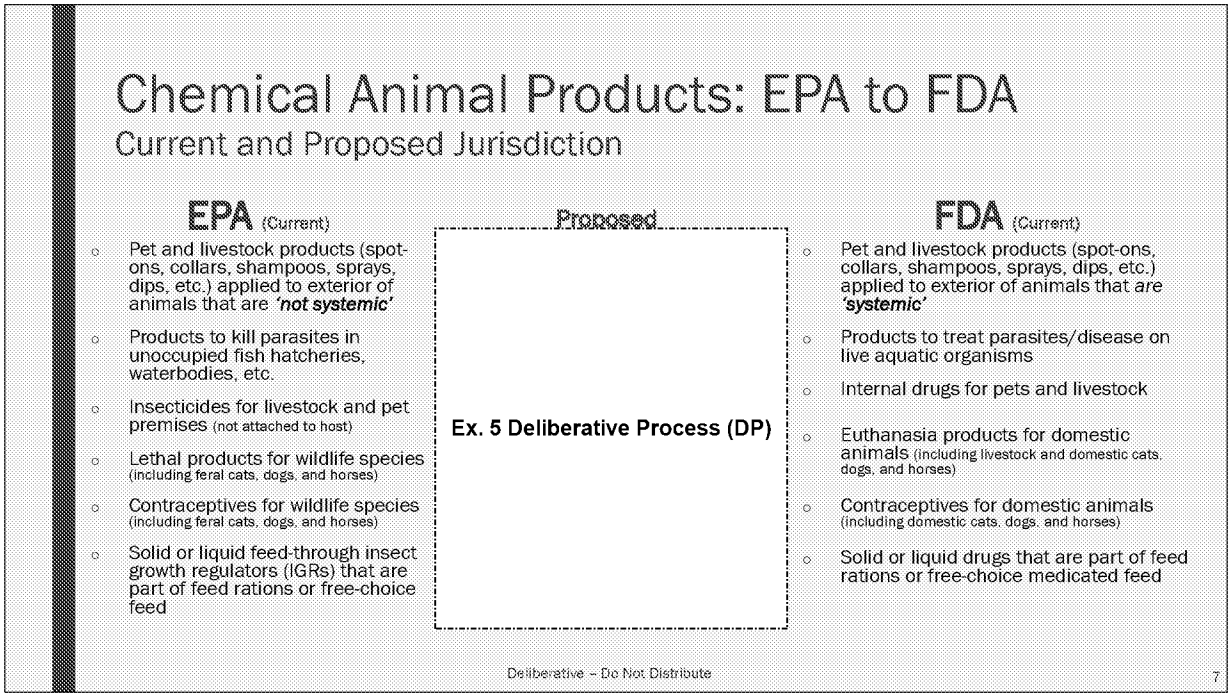
**Ex. 5 Deliberative Process (DP)**

# Chemical Animal Products:
## Challenges with Current Paradigm

**Ex. 5 Deliberative Process (DP)**




FIFRA is location-based statute. Ex. 5 Deliberative Process (DP)

**Ex. 5 Deliberative Process (DP)**

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# Chemical Animal Products: EPA to FDA

## Current FDA Staff Opinions

**EPA** (Current)

- Pet and livestock products (spot-ons, collars, shampoos, sprays, dips, etc.) applied to exterior of animals that are ***'not systemic'***
- Products to kill parasites in unoccupied fish hatcheries, waterbodies, etc.
- Insecticides for livestock and pet premises (not attached to host)
- Lethal products for wildlife specie (including feral cats, dogs, and horses)
- Contraceptives for wildlife species (including feral cats, dogs, and horses)
- Solid or liquid feed-through insect growth regulators (IGRs) that are part of feed rations or free-choice feed

**Ex. 5 Deliberative Process (DP)**

## Opportunities

# Ex. 5 Deliberative Process (DP)

# Path Forward:
## GE and Chemical Animal Products

**Ex. 5 Deliberative Process (DP)**